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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,667	01/10/2005	Annalisa Delnevo	07552.0052-00000	9403
22852 7590 04/12/2007 FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			EXAMINER HALL, DEANNA K	
			ART UNIT 3767	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/12/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/520,667	DELNEVO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Deanna K. Hall	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 10 January 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date: _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>February 7, 2005</u>  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Information Disclosure Statement*

1. The information disclosure statement (IDS) submitted on February 7, 2005 is in compliance with the provisions of 37 CFR 1.97(b). Accordingly, the IDS is being considered by the Examiner.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Sorenson et. al. (US 6,913,590) ("Sorenson").** Sorenson discloses:

a first **25, 45, 55** and second **30, 40, 50** lateral portion designed to hold corresponding portions of the transport line **15**; a rigid cross-piece **10, 20** for connecting the lateral portions; wherein the first lateral portion incorporates a continuous fluid separator **25** capable of separating fluid into a gaseous portion and a liquid portion **C6**  
**L35-54.**

4. **Claim 32 is rejected under 35 U.S.C. 102(b) as being anticipated by Ruschke (US 4,298,358).** Ruschke discloses:

a gas-liquid separator, comprising: a containing body **10** having at least one inlet **20** for receiving a fluid and at least a first outlet **22** for receiving a liquid portion of said fluid, said containing body affording internally thereof a fluid passage **28**, **Fig. 1** between said at least one inlet and said first outlet; at least one filtering element **24** arranged internally of said fluid passage having a side which faces said first outlet, and a side which faces said at least one inlet, for receiving said fluid and transferring only liquid towards said first outlet, dividing said fluid passage into an upstream portion thereof, situated between said at least one inlet and said filtering element, and a downstream portion thereof situated between said filtering element and said first outlet **Fig. 1**; at least a second outlet, being a vent **38**, operatively associated with said upstream portion of said fluid passage, for receiving a gaseous portion of said fluid.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. **Claims 1-14, 16, 18-19, 26, 28-31, 33, 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruschke (US 4,298,358) in view of Levin et al. (US 6,887,214) ("Levin").**

Ruschke discloses a majority of the elements to follow but does not directly show a support element. Levin, in the analogous art, teaches:

With reference to claims 1, 6, 7, 18, 19, 29, 30: a first and a second lateral portion designed to hold corresponding portions of the transport line to delimit at least a first length of tubing **121**; and a rigid cross-piece for connecting the lateral portions; wherein in Levin the first lateral portion incorporates a blood filter **111** rather than a continuous fluid separator capable of separating fluid into a gaseous portion and a liquid portion it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute a fluid separator for a blood filter. The object of Ruschke's invention is to provide a filter which makes the fluid being administered more suitable for living subjects **Ruschke C1 L8-13**. Likewise, the extracorporeal blood treatment of Levin makes a living subjects blood more suitable for him by removal of excessive fluids from it **Levin C1 L8-11**. Thus, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the device of Levin with the fluid separator as taught by Ruschke for administering more suitable fluids to living subjects.

The first length of tubing **121** has a curved shape **See Figs. 5, 6** and the body of the filter, the rigid cross-piece and the second lateral portion are made in a single piece with the cross-piece and tubing being parallel **See Figs. 5, 6**. The object of Ruschke's invention is to provide a fluid filter, which separates gas from liquid in a fluid stream and vents the gas, in a hanging position in a parenteral solution administration set **C1 L8-10**;

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**C8 L60-63.** Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the device of Ruschke with the support element as taught by Levin since adding the support element will stabilize the fluid filter for use in a parenteral solution administration set **C1 L8-10; C8 L60-63.**

Ruschke discloses:

2. a fluid separator **10** which comprises a containing body **10** having: at least one inlet **20** for receiving a fluid; at least a first outlet **22** for receiving a liquid portion of said fluid; selector means **24** interposed between said inlet and said first outlet and capable of continuously separating fluid into a gaseous portion and a liquid portion.
3. a second outlet **38** for receiving the gaseous portion of said fluid.
4. at least one hydrophilic membrane **24** having one side facing said first outlet and one side facing said at least one inlet, for receiving said fluid **C5 L3-12; Fig. 1** and transferring only liquid towards said first outlet **C5 L57-59.**
5. at least one hydrophobic membrane **40** having one side facing said second outlet and one side facing said inlet, for receiving said fluid and transferring only gas towards said second outlet **C5 L54-C6 L9.**

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8. a base **12** and a cover **14** portion, interacting with each other **C5 L40-48** to form a passage **28, Fig. 1** for fluid between said inlet and said first and second outlets.

9. said base forms a through channel **46** for putting said passage into fluid communication with an exterior, said hydrophobic membrane operating in said channel  
**See Figs. 1, 5 ,6.**

10. said base comprises an incorporated first tubular connecting element **22, C4, L27-29.**

11. said cover portion comprises an incorporated second tubular connecting element **20** having an axis of extension inclined with respect to that of said first tubular connecting element.

12. said hydrophilic membrane is interposed between said base and said cover portion, and extends essentially throughout said containing body **C6 L34-36, Fig. 1.**

13. each of said base and said cover portion comprises corresponding base walls and corresponding perimeter edges emerging from said base walls, said hydrophilic membrane extending parallel to said base walls in a position separated from said base walls **Fig. 1.**

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14. said containing body has a plurality of projections **28** emerging from said base wall of said base **C5 L13-25, Fig. 2.**

16. said base projections comprise teeth distributed uniformly over a surface of said base wall of said base **C5 L13-25.**

26. said containing body internally defines a fluid passage between said separator inlet and said first outlet, said hydrophobic membrane being situated in an upper zone of a fluid passage portion located upstream of said hydrophilic membrane, said hydrophobic membrane facing upwards, with reference to a use configuration of said support element, in which configuration said first length of tubing has a vertical lie plane **C5 L64-C6 L5, Fig. 1.**

28. said hydrophobic membrane **40** is located superiorly with respect to an upper point of the operative surface of said hydrophilic **24** membrane **Fig. 1.**

31. said hydrophilic membrane has a vertical lie plane, with reference to a use configuration in which said first length of tubing has a vertical lie plane **C5 L64-C6 L5, Fig. 1.**

33. said at least said second outlet is situated in an upper zone of said upstream portion of said fluid passage, with reference to a use configuration of said separator **Fig. 1.**



35. said filtering element is hydrophilic **24**, and flat, with a lie plane arranged vertically, with reference to a use configuration of said separator **Fig. 1**.

36. a hydrophobic element **40** operating on said second outlet, said filtering element and said hydrophobic element being flat and having lie planes arranged one transversally with respect to another **Fig. 1**.

37. said at least one fluid inlet is arranged in a lower zone of said upstream portion of said fluid passage, with reference to a use configuration of said separator **Fig. 1**.

38. said containing body comprises at least two base walls, which delimit said fluid passage and which face opposite sides of said filtering element, said filtering element being distanced from said base walls, a plurality of projections **28** emerging from said base walls defining two rest planes for said opposite sides of said filtering element **C5 L13-25, Fig. 2**.

7. **Claims 15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruschke in view of Levin and further in view of Stankowski et al. (US 5,439,587) ("Stankowski").** The Ruschke/Levin combination shows as discussed above. However, the projections in Ruschke 28 are only on the base side. Ruschke does not directly show a plurality of projections emerging from the cover portion and

spaced angularly to guide the flow of liquid towards the first outlet. Stankowski, in the analogous art, teaches projections emerging from the cover portion to guide the flow of liquid towards the first outlet **Stankowski C3 L23-55**. Therefore it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the device of Ruschke with the cover projections as taught by Stankowski for directing the liquid toward the outlet port **Ruschke C5 L26-39**.

8. **Claims 20-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruschke in view of Levin and further in view of Raines (US 4,310,017).** The Ruschke/Levin combination shows an umbrella valve 46 predisposed to prevent a flow in the transport line which is inverse to a desired direction. However, the valve of Ruschke does not directly show it being located in the pathway of the liquid portion after the liquid portion has been separated from the gaseous portion. Raines, in the analogous art, teaches a check valve **20** for use with IV administration sets. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the check valve an integral component of the liquid pathway since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893).

9. **Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ruschke in view of Levin and further in view of Vadnay et al. (US 4,341,538)**

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**("Vadnay"). Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ruschke in view of Vadnay.** Ruschke shows as discussed above. Ruschke does not directly show a passage section which increases in a direction towards the hydrophobic membrane. Vadnay, in the analogous art, teaches a passage which increases in a direction towards the hydrophobic membrane **See Figs. 4, 8.** Therefore it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the device of Ruschke with the asymmetrical passage as taught by Vadnay for separating gas from liquid in a fluid stream **Ruschke C1 L8-10.**

### ***Claim Rejections - 35 USC § 112***

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. **Claims 39-40 are rejected under 35 U.S.C. 112, second paragraph,** as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deanna K. Hall whose telephone number is 571-272-2819. The examiner can normally be reached on M-F 8:00am-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

dkh

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